REMARKS

Claims 1 and 11 were modified to explicitly include the "means to homogenize/scatter the radiation from the radiation source". This more carefully describes the emphasis on diffuse radiation from the diodes or other sources on the flexible substrate. We have added a new claim 12 which identifies another embodiment for the means to homogenize/scatter radiation.

Examiner contends that claims 1-4, 7 and 9-11 are anticipated by U.S. Patent No. 5,800,478 by Chen et al ('478). Applicant respectfully disagrees. Patent '478 does disclose a plurality of diodes on the distal end of a probe, but fails to provide means for emitting a diffuse radiation pattern that is large compared to the probe or other substrate. Patent '478 relies on the shape of the substrate used to determine the radiation pattern, and thus requires that a special substrate be constructed for each body area. As described in patent '478, the "flexible substrate changes size and shape as necessary to maintain the light sources in close proximity with the treatment site". (col. 4, line 50) Producing a variety of differently shaped probes for different body areas can prove time consuming and expensive. In contrast, the present invention provides for a radiation source emitting a large area diffuse radiation pattern that may be used for a more diverse range of treatments. With the present invention, a greater variety of treatment sites may be treated with one embodiment, because the emitted radiation pattern can effectively reach the treatment site without the need for close physical proximity. Thus, the present invention is distinct from '478 in that it utilizes a means to homogenize/scatter a diffuse radiation pattern to reach tissue, rather than applying a device that conforms in shape and must be in close proximity to the treated tissue.

Patent '478 describes a number of embodiments, which are briefly described below to illustrate the need for close proximity between the probe and treated tissue, in contrast to the present invention. Figures 1-13 are described in the context of tumor irradiation wherein a tumor is pierced and the probe is guided into a tumor or other solid tissue mass. The light sources on the probe are in close proximity to the diseased tissue. Another example is shown in figures 14-16, wherein a plurality of flexible probes are splayed outward for treatment of the bladder. These probes, which may also take the form of loops, spread out so that the light sources are in close proximity to the bladder wall. The present invention contemplates irradiating a body cavity such as the bladder with a diffuse radiation pattern, obviating the need for such a complex and

specialized device. Also disclosed by '478 are flexible sheet probes, which are folded prior to insertion and unfolded within the body, as is illustrated well in figures 17-21, which further demonstrate that '478 relies on physical proximity, rather than radiation pattern, to provide radiation to a treatment site. Figures 22-26 illustrate embodiments where the sheet probe is rolled prior to insertion and unrolled at the treatment site. Figures 29-35 show a cylindrical configuration of the flexible sheet probe. In this configuration, the sheet is constrained and inserted into a body lumen. The constraint is released, allowing the sheet to expand so as to physically contact the lumen wall. These embodiments can also be wrapped around a lumen to contact and treat exterior lumen walls. Figures 36-42 illustrate an embodiment where an esophageal or intestinal tumor is treated. These embodiments, utilizing probes that may not come into full physical contact, nonetheless are limited to areas where a tumor is large enough to significantly narrow the passage to receive full radiation. Figures 43-45 illustrate further embodiments for arterial and cardiological use, which also appear to require insertion of the probe so that the light sources are in very close proximity to the treatment site.

The above descriptions demonstrate a significant difference between '478 and the present invention, namely that the probes discussed in '478 require physical contact or close proximity for the probes to be effective. This requires many separate designs for different treatment modalities. The present invention is not constrained in this manner, in that the probe described in the present invention provides a means to diffuse (homogenize/scatter) a relatively large radiation pattern that can effectively treat a variety of anatomical areas.

For the above reasons, the present invention is distinctly different from '478, and is thus not anticipated by '478, nor is it made obvious.

As to U.S. Pat. No. 5,468,238 by Mersch ('238), this patent describes an endoscopic device with a remotely powered radiation source located at the distal end of the endoscope. The laser beam produced by the diode is used to "both coagulate and cut tissue in an endoscopic procedure." (col. 1, lines 53-54) Patent '238 does not provide a means to create a diffuse radiation pattern, which is the primary focus of the present invention. As described in claim 1 of the present invention, the radiation source "provides a diffuse radiation pattern across a section of body tissue". (emphasis added) Patent '238 only provides for a diode laser source at the distal end of

the instrument. Furthermore, '238 appears to be primarily intended for use as a cutting or coagulating tool. Cutting and coagulating tissue requires a beam with a sufficient energy density to burn tissue, and would thus require a focused rather than a diffuse beam. All embodiments described in '238 focus the beam to a distinct point with the aid of focusing means such as a lens. A diffuse beam would render '238 useless for its disclosed purpose. A focused beam such as that disclosed in '238 would be ineffective for PDT treatments such as those contemplated by the present invention. Thus, because '238 does not provide for a diffuse radiation delivery pattern, it does not anticipate the present invention.

Since '478 does not anticipate nor make obvious the use of a means to homogenize/scatter radiation from the distally placed source(s), the addition of Berry, US Pat No. 6,254,549 B1 which mentions a chemiluminescent cell, does not materially affect any of the currently listed claims.

With these changes and remarks, it is believed that the disclosure is now in condition for allowance. Reconsideration is respectfully requested. An early and favorable response is earnestly solicited. Thank you.

Respectfully submitted,

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Bolesh J. Skutnik, PhD, JD
Reg. No. 36,347
Attorney for Applicants

CeramOptec Industries, Inc.
515 Shaker Road
East Longmeadow, MA 01028
Phone: (413) 525-8222

Fax: (413) 525-0611